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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,322	06/09/2006	Scott Eugene Conner	X16589	5343

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ELI LILLY & COMPANY
PATENT DIVISION
P.O. BOX 6288
INDIANAPOLIS, IN 46206-6288

EXAMINER	
NOLAN, JASON MICHAEL	
ART UNIT	**PAPER NUMBER**
1626	

NOTIFICATION DATE	DELIVERY MODE
04/04/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@lilly.com

Office Action Summary	Application No.	Applicant(s)	
	10/596,322	CONNER ET AL.	
	Examiner	Art Unit	
	JASON M. NOLAN	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,4-8,13,16,23,25,28,30,33-35,43,44,49,52 and 54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,13,30 and 35* is/are rejected.

7)☒ Claim(s) *2,4-8,16,23,25,28,33,34,43,44,49,52 and 54* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *06/09/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is responsive to Applicants Preliminary Amendment, filed **10/19/2007**. **Claims 2, 4-8, 13, 16, 23, 25, 28, 30, 33-35, 43, 44, 49, 52, & 54** are pending in the instant application; of which, **Claim 2** is currently amended. **Claims 1, 3, 9-12, 14, 15, 17-22, 24, 26, 27, 29, 31, 32, 36-42, 45-48, 50, 51, 53, & 55-67** are canceled.

Information Disclosure Statement

Applicants' information disclosure statement (IDS), filed on **06/09/2006** has been considered. Please refer to Applicants' copy of the 1449 submitted herein.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 13 recites the limitation "Formula I". There is insufficient antecedent basis for this limitation in the claim. "Formula I should be amended to "Formula II". Appropriate correction is required.

Claim 30 recites the limitation "hydrogen" for the variable "R1". There is insufficient antecedent basis for this limitation in the claim. R1 is limited to C1-C8 alkyl in Claim 2. Appropriate correction is required.

Claim 35 recites the limitation "aliphatic linker". There is insufficient antecedent basis for this limitation in the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 2 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the compounds of the formula (II), including pharmaceutically acceptable salts thereof; the specification is not enabled for *hydrates and solvates* thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The Nature of the Invention

The nature of the invention is the compounds of formula (II), including all pharmaceutically acceptable salts, hydrates, and solvates thereof.

The state of the prior art and the predictability or lack thereof in the art

Active pharmaceutical ingredients (APIs) are frequently delivered to the patient in the solid-state as part of an approved dosage form (e.g., tablets, capsules, etc.). Solids

provide a convenient, compact and generally stable format to store an API or a drug product. Understanding and controlling the solid-state chemistry of APIs, both as pure drug substances and in formulated products, is therefore an important aspect of the drug development process. APIs can exist in a variety of distinct solid forms, including polymorphs, solvates, hydrates, salts, co-crystals and amorphous solids. Each form displays unique physicochemical properties that can profoundly influence the bioavailability, manufacturability purification, stability and other performance characteristics of the drug. Hence, it is critical to understand the relationship between the particular solid form of a compound and its functional properties.

For ionizable compounds, preparation of salt forms using pharmaceutically acceptable acids and bases is a common strategy to improve bioavailability. However, the preparation of other solid forms such as polymorphs and solvates are not so common as to be predictable. In order to obtain patent protection on these forms, some of which may have significantly different properties and relevance as development candidates, it is essential to prepare them, identify conditions for making them and evaluate their properties as valuable new pharmaceutical materials. A large number of factors can influence crystal nucleation and growth during this process, including the composition of the crystallization medium and the processes used to generate super-saturation and promote crystallization, (Morissette *et al.* Advanced Drug Delivery Reviews **2004**, *56*, 275-300).

Amount of direction/guidance & presence or absence of working examples

The direction or guidance present in the instant specification for the preparation of pharmaceutical salts for compounds according to formula (II) is on page 19 of the specification. However, there is no direction, guidance or working examples present in the disclosure for hydrates or solvates with respect to a compound according to formula (II).

The breadth of the claims

The instant breadth of the rejected claims is broader than the disclosure, specifically; the instant claims include any solvate (including hydrate) of a compound according to formula (II).

The quantity of experimentation necessary

While the level of the skill in the pharmaceutical arts is high, it would require undue experimentation of one of ordinary skill in the art to prepare any solvate for a compound according to formula (II) as instantly claimed. The science of producing pharmaceutically acceptable hydrates and solvates has not evolved such that, without guidance or working examples in the specification, the claims lack enablement. This rejection can be overcome by deletion of the words “solvates and hydrates” from **Claim 2**.

Claim Objections

Claim 33 is objected to because of the following informalities: the limitation “U is saturated" is not further limiting from the **Claim 2** definition: “U is C1-C3 alkyl." Alkyl is a saturated moiety. Appropriate correction is required.

Claim 43 is objected to because of the following informalities: the limitation “R2 is a bond" is not further limiting from **Claim 2** “R2 is a bond." Appropriate correction is required.

Claim 2 is objected to because of the following informalities:

1) The definition of **R1** is C1-C8 alkyl, should this include H? *See* 112-rejection of **Claim 30** above;

2) In the definition of **X**, there should be a space between "Oand";

3) In the definition of **Y**, there should be a space between “Oand”;

4) In the definition of **R9**, there should be a space between “hydrogenand”;

5) The definition of **R10** is CF, which is not a descriptive functional group. Should it be CF_3? and

6) The definition of **R32** includes a bond, which doesn’t link to anything; “bond” should be deleted. Appropriate correction is required.

Claims 4-8, 16, 23, 25, 28, 34, 44, 49, 52, & 54 are objected to as being dependent upon a rejected base, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Allowable Subject Matter

The present invention pertains to the indazoles of formula II in **Claim 2** and methods of using these compounds for the treatment of diabetes. The compounds according to formula II are free of the prior art; nothing known in the art anticipates or renders the compounds of the instant application obvious. The closest prior art related to the formula II are compounds described by Conner *et al.* (WO 2004/063155 A1, *see* IDS). The compounds of the instant application are distinct from the prior art because the instant compounds are 1,2-benzo-fused-diazoles, whereas the prior art compounds are 1,3-benzo-fused-diazoles.

One skilled in the art would be enabled to make and use the compounds taught herein for the purpose of treating diabetes mellitus using the teachings of the Specification in conjunction with the teachings in the prior art.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jason M. Nolan, Ph.D.** whose telephone number is **(571) 272-4356** and electronic mail is Jason.Nolan@uspto.gov. The examiner can normally be reached on Mon - Fri (9:00 - 5:30PM). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph M^{c}Kane** can be reached on **(571) 272-0699**. The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Jason M. Nolan, Ph.D./

Examiner, Art Unit 1626

/Rebecca L Anderson/

Primary Examiner, Art Unit 1626